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AUGMENTIN amoxicillin/clavulanate potassium

Brief Summary of Prescribing Information

Indications and Usage: AUGMENTIN® is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below.

Lower Respiratory Infections caused by β -lactamase-producing strains of *Haemophilus influenzae* and *Branhamella catarrhalis*.
Otitis Media caused by β -lactamase-producing strains of *Branhamella catarrhalis* and *Haemophilus influenzae*.
Sinusitis caused by β -lactamase-producing strains of *Branhamella catarrhalis* and *Haemophilus influenzae*.

Skin and Skin Structure Infections caused by β -lactamase-producing strains of *Staphylococcus aureus*, *E. coli*, and *Klebsiella* spp.
Urinary Tract Infections caused by β -lactamase-producing strains of *E. coli*, *Klebsiella* spp. and *Enterobacter* spp.

While AUGMENTIN® is indicated only for the conditions listed above, infections caused by ampicillin susceptible organisms are also amenable to AUGMENTIN® treatment due to its amoxicillin content. Therefore, mixed infections caused by ampicillin susceptible organisms and β -lactamase-producing organisms susceptible to AUGMENTIN® should not require the addition of another antibiotic. Bacteriologic studies, to determine the causative organisms and their susceptibility to AUGMENTIN®, should be performed together with any indicated surgical procedures.

Therapy may be instituted prior to obtaining the results from bacteriologic and susceptibility studies to determine the causative organisms and their susceptibility to AUGMENTIN® when there is reason to believe the infections may involve any of the β -lactamase-producing organisms listed above. Once the results are known, therapy should be adjusted, if appropriate.

Contraindications: A history of allergic reactions to any penicillin is a contraindication. **WARNINGS:** SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTOID) REACTIONS HAVE BEEN REPORTED IN PATIENTS ON PENICILLIN THERAPY. ALTHOUGH ANAPHYLAXIS IS MORE FREQUENT FOLLOWING PARENTERAL THERAPY, IT HAS OCCURRED IN PATIENTS ON ORAL PENICILLINS. THESE REACTIONS ARE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY AND/OR A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS. THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE REACTIONS WHEN TREATED WITH CEPHALOSPORINS. BEFORE INITIATING THERAPY WITH ANY PENICILLIN, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS ALLERGIC REACTIONS TO PENICILLINS, CEPHALOSPORINS, OR OTHER ALLERGENS. IF AN ALLERGIC REACTION OCCURS, AUGMENTIN® SHOULD BE DISCONTINUED AND THE APPROPRIATE THERAPY INITIATED. SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE, OXYGEN, INTRAVENOUS STEROID, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS INDICATED.

Precautions: General: While AUGMENTIN® possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic and hematopoietic function is advisable during prolonged therapy.

A high percentage of patients with mononucleosis who receive ampicillin develop a skin rash. Thus, ampicillin class antibiotics should not be administered to patients with mononucleosis.

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

Drug/Laboratory Test Interactions: Oral administration of AUGMENTIN® will result in high urine concentrations of amoxicillin. High urine concentrations of ampicillin may result in false positive reactions when testing for the presence of glucose in urine using Clinitest® Benedict's Solution or Fehling's Solution. Since this effect may also occur with amoxicillin and therefore AUGMENTIN® it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix® or Tenos®) be used.

Following administration of ampicillin to pregnant women a transient decrease in plasma concentration of total conjugated estradiol, estradiol-glucuronide, conjugated estrone and estradiol has been noted. This effect may also occur with amoxicillin and therefore AUGMENTIN®.

Drug Interactions: Probenecid decreases the renal tubular secretion of ampicillin. Concurrent use with AUGMENTIN® may result in increased and prolonged blood levels of ampicillin.

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rash in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rash is due to allopurinol or the hyperuricemia present in these patients. There are no data with AUGMENTIN® and allopurinol administered concurrently.

AUGMENTIN® should not be co-administered with Antabuse® (disulfiram). **Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential.

Pregnancy (Category B): Reproduction studies have been performed in mice and rats at doses up to ten (10) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus from AUGMENTIN®. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery: Oral ampicillin class antibiotics are generally poorly absorbed during labor. Studies in guinea pigs have shown that intravenous administration of ampicillin decreased the uterine frequency of contractions, length of contractions and duration of contractions. However, it is not known whether the use of AUGMENTIN® in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Nursing Mothers: Ampicillin class antibiotics are excreted in the milk; therefore, caution should be exercised when AUGMENTIN® is administered to a nursing woman.

Adverse Reactions: AUGMENTIN® is generally well tolerated. The majority of side effects observed in clinical trials were of a mild and transient nature and less than 3% of patients discontinued therapy because of drug related side effects. The most frequently reported adverse effects were diarrhea/loose stools (9%), nausea (3%), vomiting (1%), skin rashes and urticaria (3%), and vaginitis (1%).

The overall incidence of side effects, and in particular diarrhea, increased with the higher recommended dose. Other less frequently reported reactions include: abdominal discomfort, flatulence and headache.

The following adverse reactions have been reported for ampicillin class antibiotics:

Gastrointestinal: Diarrhea, nausea, vomiting, gastritis, stomatitis, glossitis, black hairy tongue, enterocolitis and pseudomembranous colitis.

Hypersensitivity reactions: Skin rashes, urticaria, erythema multiforme and an occasional case of exfoliative dermatitis have been reported. These reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, the drug should be discontinued, unless the opinion of the physician warrants otherwise. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions can occur with oral penicillin (See Warnings).

Local: A moderate (use in SCOT and/or SCPT) has been noted in patients treated with ampicillin class antibiotics as well as with AUGMENTIN® but the significance of these findings is unknown.

Hemic and Lymphatic Systems: Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and agranulocytosis have been reported during therapy with penicillin. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1% of the patients treated with AUGMENTIN®.

Dosage: Adults: The usual adult dose is one AUGMENTIN® 250 tablet every eight hours. For more severe infections and infections of the respiratory tract, the dose should be one AUGMENTIN® 500 tablet every eight hours.

Since both the AUGMENTIN® 250 and 500 tablets contain the same amount of clavulanic acid (125mg, as the potassium salt), two AUGMENTIN® 250 tablets are not equivalent to one AUGMENTIN® 500 tablet. Therefore, two AUGMENTIN® 250 tablets should not be substituted for one AUGMENTIN® 500 tablet for treatment of more severe infections.

Children: The usual dose is 40 mg/kg/day based on amoxicillin component, in divided doses every eight hours. For otitis media, sinusitis and other more severe infections, the dose should be 40 mg/kg/day, based on the amoxicillin component, in divided doses every eight hours. Also available as AUGMENTIN® 125 and 250 chewable tablets.

Children weighing 40 kg and more should be dosed according to the adult recommendations.

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Brief Summary: ANAPROX® (naproxen sodium)

Indications: Relief of mild to moderate pain; treatment of primary dysmenorrhea.

Contraindications: Patients who have had allergic reactions to NAPROSYN or ANAPROX or in whom aspirin or other NSAIDs induce the syndrome of asthma, rhinitis, and nasal polyps.

Warnings: GI bleeding, sometimes severe, and occasionally fatal, has been reported. Do not give to patients with active peptic ulcer unless potential benefit outweighs risk. Administer to those and others with history of GI disease only under close supervision.

Precautions: DO NOT GIVE NAPROSYN® (NAPROXEN SODIUM) CONCOMITANTLY WITH ANAPROX® (NAPROXEN SODIUM) SINCE BOTH CIRCULATE IN PLASMA AS THE NAPROXEN ANION. Because anaphylactic reactions usually occur in patients with a history of such reactions, question patients for asthma, nasal polyps, urticaria, and hypotension associated with NSAIDs before starting therapy. If such symptoms occur, discontinue the drug. Acute interstitial nephritis with hematuria, proteinuria, and nephrotic syndrome has been reported. Patients with impaired renal function, heart failure, liver dysfunction, taking diuretics, and the elderly are at greater risk of overt renal decompensation. If this occurs, discontinue the drug. Use with caution and monitor serum creatinine and/or creatinine clearance in patients with significantly impaired renal function. Use caution in patients with baseline creatinine clearance less than 20 mL/minute. Use caution when high doses are required in the elderly or in patients with chronic alcoholic liver disease or cirrhosis. With NSAIDs, borderline elevations of liver tests may occur in up to 15% of patients. They may progress, remain unchanged, or diminish with continued therapy. Elevations of SGPT or SGOT occurred in controlled clinical trials in less than 1% of patients. Severe hepatic reactions, including jaundice and fatal hepatitis, have been reported rarely. If liver disease develops or if systemic manifestations occur (e.g., eosinophilia or rash), discontinue therapy. If steroid dosage is reduced or eliminated during therapy, do so slowly and observe patients closely for adverse effects, including adrenal insufficiency and exacerbation of arthritis symptoms. Determine hemoglobin values frequently for patients with initial values of 10 grams or less who receive long-term therapy. Peripheral edema has been reported. For patients with restricted sodium intake, note that each tablet contains approximately 25 mg (1 mEq) sodium. Use with caution in patients with fluid retention, hypertension or heart failure. The drug's antipyretic and anti-inflammatory activities may reduce fever and inflammation, diminishing their diagnostic value. Conduct ophthalmic studies soon after starting therapy and at periodic intervals if the drug is used for an extended period.

Information for Patients: Patients should use caution for activities requiring alertness if they experience drowsiness, dizziness, vertigo or depression during therapy.

Drug Interactions: Use caution when giving concomitantly with coumarin-type anticoagulants; a hydantoin, sulfonamide or sulfonylurea, furosemide; lithium; beta-blockers; probenecid; or methotrexate.

Drug/Laboratory Test Interactions: The drug may decrease platelet aggregation and prolong bleeding time or increase urinary values for 17-ketogenic steroids. Temporarily stop therapy for 72 hours before doing adrenal function tests. The drug may interfere with urinary assays of 5HIAA.

Carcinogenesis: A 2-year rat study showed no evidence of carcinogenicity.

Pregnancy: Category B. Do not use during pregnancy unless clearly needed. Avoid use during late pregnancy.

Nursing Mothers: Avoid use in nursing mothers.

Pediatric Use: Indications and dosage have not been established.

Adverse Reactions: Incidence Greater Than 1%: GI: The most frequent complaints related to the GI tract: constipation; heartburn; abdominal pain; nausea; dyspepsia, diarrhea, stomatitis. CNS: headache, dizziness, drowsiness; light-headedness, vertigo. Dermatologic: itching (pruritus); skin eruptions; ecchymoses; sweating, purpura. Special Senses: tinnitus; hearing disturbances; visual disturbances. Cardiovascular: edema; dyspnea; palpitations. General: thirst. *Incidence of reported reaction 3%-9%. Where unmarked, incidence less than 3%. Incidence Less Than 1%: Probable Causal Relationship: GI: abnormal liver function tests, GI bleeding and/or perforation, hematemesis, jaundice, melena, peptic ulceration with bleeding and/or perforation, vomiting. Renal: glomerular nephritis, hematuria, interstitial nephritis, nephrotic syndrome, renal disease. Hematologic: eosinophilia, granulocytopenia, leukopenia, thrombocytopenia. CNS: depression, dream abnormalities, inability to concentrate, insomnia, malaise, myalgia and muscle weakness. Dermatologic: alopecia, photosensitive dermatitis, skin rashes. Special Senses: hearing impairment. Cardiovascular: congestive heart failure. Respiratory: eosinophilic pneumonitis. General: anaphylactoid reactions, menstrual disorders and fever. Causal Relationship Unknown: Hematologic: agranulocytosis, aplastic anemia, hemolytic anemia. CNS: cognitive dysfunction. Dermatologic: epidermal necrolysis, erythema multiforme, Stevens-Johnson syndrome, urticaria. GI: ulcerative stomatitis. Cardiovascular: vasculitis. General: angioneurotic edema, hyperglycemia, hypoglycemia.

Overdosage: May have drowsiness, heartburn, indigestion, nausea, vomiting. Empty stomach and use usual supportive measures. Prompt administration of 5 grams activated charcoal may reduce drug absorption.

Dosage and Administration for Mild to Moderate Pain, Dysmenorrhea and Acute Tendinitis and Bursitis: The recommended starting dose is two 275 mg tablets, followed by one 275 mg tablet every 6 to 8 hours, as required. The total daily dose should not exceed 5 tablets (1375 mg).

Caution: Federal law prohibits dispensing without prescription. See package insert for full Prescribing Information.

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